DEPARTMENT OF HEALTH & HUMAN SERVICES

94363d

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 15, 2003 W/L 04-04

Barry M. Tydings
President/CEO
Drug Free Enterprises
5302 Derry Ave., Ste A
Agoura Hills, CA 91301

Dear Mr. Tydings:

We are writing to you because an investigator from the United States Food and Drug Administration (FDA) conducted an inspection of your facility located in Agoura Hills, California between January 21 and February 11, 2003, which determined that your firm is a specification developer, and by regulation [Title 21, Code of Federal Regulations (CFR), Section 807.3(d)(3)] a manufacturer of drugs-of-abuse test kits. Information collected during the inspection revealed serious regulatory problems involving your DRUGCHECK NO STEP-ONSITE drugs-of-abuse test kits. Also, during our inspection between June 17 and 30, 2003 additional serious regulatory problems involving your consumer study for your drugs-of-abuse kits were revealed.

Under a United States Federal law, the Federal Food, Drug and Cosmetic Act (the Act), these kits are considered to be medical devices because they are intended to be used to diagnose or treat a medical condition (Section 201(h) of the Act).

Our inspections revealed that your devices are adulterated under section 501(h) of the Act, in that the methods used in, or facilities or controls used for, the manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System (QS) regulation, as specified in Title 21, CFR, Part 820. Significant deficiencies observed include, but are not limited to the following:

- Your firm lacks adequate design controls. Specifically, you do not have documentation that your marketed product was developed following the approved

design or that all subsequent changes made in your drugs-of-abuse test kits have been adequately defined and evaluated. Nor do you have documentation of complete manufacturing specifications for your contract manufacturer. [Title 21 CFR §§ 820.30 and 820.3(k)]

- A quality system has not been fully implemented and maintained at all levels of the organization. Specifically, your quality policy and objectives and your quality plan have not been fully established. [Title 21 CFR § 820.20]

- Document control procedures have not been fully implemented and maintained. Specifically, the device master records for product codes 60300, 60500, 65500-4 and 60505 are incomplete, change control records are not maintained on-site and complaint documents received by field representatives are not maintained at the firm. [Title 21 CFR §§ 820.181 and 820.198]

- Your device history records are inadequate. Specifically, you are not maintaining acceptance records that demonstrate your drugs-of-abuse test kits are manufactured in accordance with the approved device master record. [Title 21 CFR § 820.184]

- Failure to establish and maintain procedures to ensure all purchased or otherwise received product and services conform to specified requirements. Specifically, your firm has not evaluated and documented the abilities of your supplier and consultant to meet specified requirements, including quality requirements and your firm does not have a complete written contract with the contract manufacturer who produces your drugs-of-abuse kits or the consultant who oversees your firm's quality system. [Title 21 CFR § 820.50]

Additional CGMP deficiencies were observed and reported during our January 21 - February 11, 2003 inspections. Your written response of March 5, 2003 provided documentation of correction of your lack of written procedures for CAPA, complaints and required audits. Review of the supporting documentation submitted for these corrections revealed several are incomplete, do not have implementation dates, contain minor errors and conflicting time periods for your Management Review. We strongly suggest you re-evaluate your written procedures and correct these deficiencies.

The Act requires that manufacturers of medical devices obtain marketing clearance for their devices from FDA before they may be offered for sale. This helps protect the public health by ensuring that newly introduced medical devices are safe and effective or substantially equivalent to other devices already legally marketed in this country. Furthermore, once marketing clearance is obtained, products must conform to the approved application.

Two of your kits (Product Codes 60900 and 60903) are adulterated under section 501(f)(1)(B) and misbranded under section 502(o) in that they include testing for tricyclic

antidepressants. Your cleared pre-market notification (K012390) does not include testing for this drug category. Products including testing for tricyclic antidepressants are unapproved, may not be legally marketed, and should be withdrawn from the market. You must submit a new 510(k) and obtain FDA clearance before you can make such a claim.

At least one of your kits (Product Code 60903) is also adulterated under section 501(f)(1)(B) and misbranded under section 502(o) in that it includes testing for opiates at a cut-off level of 300 ng/ml. Your cleared pre-market notification (K012390) identifies an opiate cut-off level of 2000 ng/ml. Again, products including testing for opiates at a cut-off level of 300 ng/ml are unapproved, may not be legally marketed, and should be withdrawn from the market. You must submit a new 510(k) and obtain FDA clearance before you can make such a claim.

Your DRUGCHECK NO STEP-ONSITE drugs-of-abuse test kits are misbranded within meaning of Section 502(b) of the Act in that the devices are in package form and their labels fails to contain the name and address of the manufacturer or distributor.

This letter is not intended to be an all-inclusive list of violations. As a manufacturer of medical devices it is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the two FDA-483s, Inspectional Observations, issued at the close of our inspections may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventative action on your Quality System.

You should know that these serious violations of the law may result in the FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further manufacturing of the product, or assessing civil money penalties. Also Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

Additionally, we note that you have changed the name of the drug-of-abuse test kits cleared in the original 510(k) from Drug Free Enterprises NexStp Drug Check to DRUGCHECK NO STEP-ONSITE. While FDA was reviewing the 510(k) for this device we advised you that we found your proposed "NO STEP" name to be misleading. Your device received FDA clearance after you advised that the name of this device would be changed to NexStp Drug Check. Now you have gone back to using a name which the Agency found to be misleading.

It is necessary for you to take action on this matter now. Please let this office know, in writing, what steps you have taken to correct the problems within fifteen (15) working days of receipt of this letter. We also ask that you provide an explanation of each step

being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made. If you have any questions or need clarification regarding this letter, you may contact Barbara Rincon, Compliance Officer at telephone number (949) 608-4439.

Products that are adulterated and/or misbranded should be removed from the market via a voluntary recall. For information and assistance with the recall of your products in distribution you may contact our Recall Coordinator, Craig Hoover at (949) 798-7730.

You should know and understand that there re many FDA requirements pertaining to the manufacture and marketing of medical devices. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting the Center for Devices and Radiological Health's Division of Small Manufacturers, International, and Consumer Assistance at 1-800-638-2041 or through the Internet at www.fda.gov.

Your reply should be directed to:

Acting Director, Compliance Branch
U.S. Food & Drug Administration
19701 Fairchild
Irvine, CA 92612

Sincerely,

Alonza Cruse
District Director

cc: [redacted]